FDA 510(k) Premarket Notification

K770005 PACEMAKER 208S

CLEARED

Feb 24, 1977
52 days to decision

K770005 · Product code: **DXY** · Cardiovascular
Source: https://www.510kdatabase.net/k770005/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Jan 3, 1977
Decision date	Feb 24, 1977
Days to decision	52 days
Third-party review	No

APPLICANT

Company	**Elema-Schonander, Inc.**
Location	Mchenry, IL, US
510(k) history	11 submissions · 11 cleared · 1977-1993